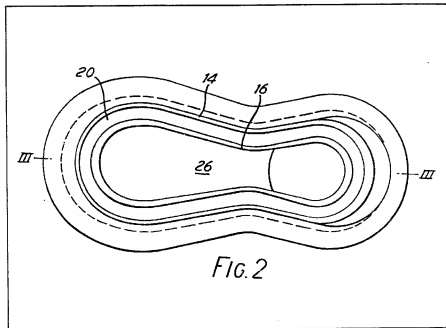
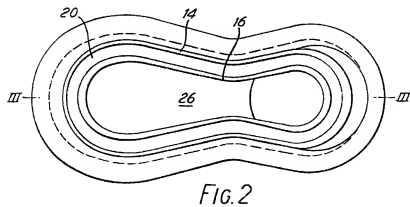
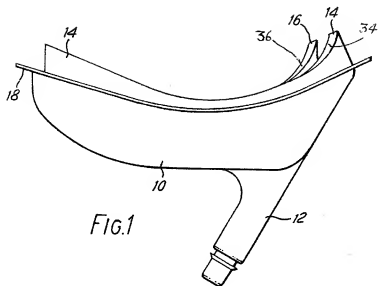


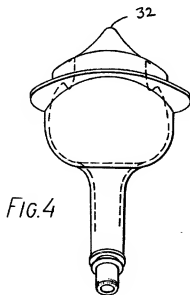
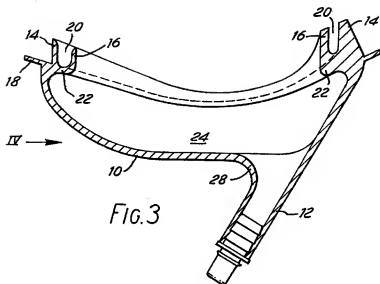
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## (54) Female incontinence device

(57) A female incontinence device is formed principally of a single piece of flexible material which has a pair of deflectable walls 14, 16 which define a channel at the periphery of the device intended to contact the wearer. The device as seen in plan has a "waisted" or approximately "8-shaped" configuration and the deflectable walls as seen in side elevation having sealing edges each of which is constituted by a pair of continuous curves, one on each side of the central longitudinal axis of the device and which extend from a high point at the front of the device to a high point at the rear of the device.







## SPECIFICATION

## Female incontinence device

- 5 This invention relates to a female incontinence device.

The prior art is replete with attempts to design a completely satisfactory female incontinence device. One of the greatest problems involved is securing adequate and reliable sealing of the device to the skin of the wearer, bearing in mind the complex shape and the numerous variations from person to person of the relevant part of the female anatomy.

One approach is that taken in U.K. Patent Application Serial No. 2 090 741 involving a seal around the urethral orifice. Another approach is typified by U.S. Patent 3 194 238 involving an attempt to make a double seal, one seal by an inner bellows structure and another seal by an outer bellows structure.

20 Numerous other attempts have been made, of which the following can be mentioned as examples:—

European Patent Application Serial No. 18749.

U.S. Patent 3 995 329

British Patent 1 522 391

25 U.S. Patent 3 613 122

U.S. Patent 3 512 185

Garman Specification 1766795

U.S. Patent 4 116 197

U.S. Patent 2 483 079

30 British Patent 1 216 682

British Patent 1 323 190

British Patent 1 144 483

British Patent 1 422 638.

Despite the claims made in these earlier documents, it has in practice proved very difficult to obtain satisfactory sealing, especially when the device is being worn by an active person. Another problem encountered but never properly solved is that with some wearers, there may well be a sudden rapid flow of urine, exiting at considerable pressure, and this gives rise to splashing, and the splashed liquid may cause soreness and maceration and also tends to reduce the security of attachment when an adhesive is used. Yet another problem is that many devices according to earlier suggestions are undesirably rigid and therefore are both uncomfortable to wear and liable to seal inadequately.

The present invention aims to provide an improved female incontinence device.

50 According to the present invention, there is provided a female incontinence device formed principally of a single piece of flexible material which has a pair of deflectable walls which define a channel at the periphery of the device intended to contact the wearer, the device as seen in plan having a "waisted" or approximately 8-shaped configuration and the deflectable walls as seen in side elevation having sealing edges each of which is constituted by a pair of continuous curves, one on each side of the central longitudinal axis of the device and which extend from a high point at the front of the device to a high point at the rear of the device.

Among the optional features of the invention, the following can be mentioned:—

- 65 1. The peripheral sealing obtained by the groove

defined by two deflectable walls can be enhanced by squeezing a liquid-repellant type of cement or adhesive into the groove, this helps to seal the periphery of the device to the person wearing it;

- 70 2. the said deflectable walls defining a specially shaped saddle configuration designed to contact the wearer between the base of the vagina and the anus and located at the rear zone of the device in order to minimise the possibility of leakage at this area, where the risk of leakage is normally greatest;
- 75 3. an undercut region located beneath the deflectable walls intended to limit splash back;
4. an overall "waisted" or "8-shaped" configuration as seen in plan to improve comfort in wear; and
- 80 5. a basin or chamber shaped to conduct all urine directly to an outlet pipe.

The non-irritant cement or adhesive material referred to above is to be understood as a material which can be squeezed from a tube or moulded by hand from a block and which when applied to moist body skin surfaces, is capable of adhesively adhering thereto for a prolonged period of time, for example well over 12 hours, and which, when so used, does not generate any allergic reaction or irritation in the majority of human beings when so adhered. One example of a suitable material is that as "STOMAHESIVE" (Registered Trade Mark) and made and sold by E. R. Squibb & Sons Inc. of U.S.A. or its subsidiary and associated companies.

95 The invention will be better understood from the following description of an illustrative embodiment, given with reference to the accompanying drawings, in which:—

Figure 1 is a side elevation of one example of a female incontinence device according to the invention;

Figure 2 is a top plan view of the device shown in Figure 1;

Figure 3 is a vertical central section taken on the line III of Figure 2; and

Figure 4 is an end view of the device looking in the direction of IV in Figure 3.

The female incontinence device illustrated in Figures 1-4 is preferably formed, moulded or shaped from a single piece of flexible material. Suitable materials are rubber of a Shore hardness of 50-55°, synthetic rubber, and flexible synthetic plastics materials. The device includes a chamber or basin 10 integral with an outlet pipe 12 and a pair of peripheral deflectable walls 14 and 16. It also has a laterally extending flange 18. This flange serves for connection of the device to a suitable woman's garment, for example a pair of conventional "stretch panties" modified by a cut out in the crotch portion shaped to receive the device. The flange 18 may be stuck or sewn to the panties, to provide a permanent attachment, or it may be attached to suitable panties by press-studs or by strips of material having inter-engaging hooks, for example the material known by the Trade Name "VELCRO".

According to an advantageous feature of the invention, the periphery of the device intended to contact the skin of the wearer is formed by a pair of deflectable walls defining a groove in which suitable adhesive material of a paste nature may be squeezed.

The use of an adhesive or cement or paste is not essential although it is preferred. The walls 14 and 16 are deflectable and are configured so that they deflect inwardly or outwardly into contact with the adjacent surface of the body of the wearer; due to this deformation they make surface rather than edge contact with the body and so tend to provide good sealing without undue discomfort.

As an alternative to this and as an alternative to inserting a paste or cement material between the walls 14 and 16, it is possible to insert largely the walls 14, 16 a gasket in the form of a soft deformable ring of thickness chosen to fit snugly between the walls; sealing is then achieved between the upper surface of such a ring, flattened by contact with the body of the wearer, and the confronting skin surface of the wearer. The groove 20 is defined by the walls 14 and 16 and as shown may be deeper and narrower at the rear end of the device (right-hand end of Figure 3) and shallower and wider at the forward end of the device. According to another particularly advantageous feature of the device, the walls 14 and 16 are supported by a portion of the material 22 which overhangs a urine receiving chamber 24 so defining an undercut region which in use acts to limit splash. In other words, liquid expelled at relatively high pressure runs up the walls of the basin and is turned to move back in a lateral or downward direction. In this way the possibility of any splash reaching the skin of the wearer is greatly reduced.

Another advantageous feature of the invention is designed to improve comfort in wear. The illustrated female incontinence device in accordance with the invention is of "waisted" or "hour glass" shape as seen in plan, as clearly illustrated in Figure 2. The upward facing opening 26 is of like shape, and its boundary is defined by the inner wall 16. As seen in side elevation, the preferred device has a sealing edge of a specially chosen configuration. Each of the two walls 14, 16 has an upper edge 34, 36 which is a complex curve, rising to a high point at the front of the device and another high point at the rear of the device, so that the overall configuration is reminiscent of that of a saddle. In particular as seen in Figure 4, the walls rise to a rounded hump or peak which, when the device is worn, is located between the base of the vagina (rearward side) and the anus. In prior art female incontinence device, this region has presented problems in obtaining effective and adequate sealing. The "waisted" configuration referred to has the result that the device is relatively comfortable to wear both in a standing position as well as a sitting position; this comfort is enhanced by the choice of a flexible rubber or rubber-type material for the device.

As can be seen best in Figures 1 and 3, the basin wall 10 defining the lower boundary of the chamber 24 is shaped so as to slope sharply away as seen at 28 in the region of outlet pipe 12. The purpose of this is to facilitate quick and unobstructed flowing away of urine into the outlet pipe 12. As shown in Figures 2 and 4, the device may be equipped with a pipe coupling element in accordance with U.K. Patent Application Serial No. 2 092 690.

To the best of Applicants' knowledge and belief, none of the extremely numerous prior attempts to

design a satisfactory female incontinence device employed the feature of a pair of deflectable walls defining a groove, none suggested using such a groove to receive a sealant, and the Applicants have moreover taken special measures in the present design to limit splash back and to render the device comfortable to wear. In particular relation to persons liable to discharge urine rapidly at high volume, it is believed that the present incontinence device will prove to be more practical and more satisfactory than prior art designs known to the Applicants. In addition, the device can be easily and cheaply manufactured, as no assembly is involved, and it is relatively simple for a user to apply it to herself particularly when attached to conventional stretch panties, it is also easy to fill the groove 20 with adhesive paste or with a gasket as described and push the incontinence device into position. To the best of Applicants' knowledge and belief, the present device offers numerous advantages which have not been simultaneously achieved by any one of the many hundreds of prior designs of female incontinence device.

#### CLAIMS (filed on 21/1/83)

1. A female incontinence device formed principally of a single piece of flexible material which has a pair of deflectable walls which define a channel or groove at the periphery of the device intended to contact the wearer, the device as seen in plan having a "waisted" or approximately "8-shaped" configuration and the deflectable walls as seen in side elevation having sealing edges each of which is constituted by a pair of continuous curves, one on each side of the central longitudinal axis of the device and which extend from a high point at the front of the device to a high point at the rear of the device.

2. A device according to claim 1 in which the peripheral sealing obtained by the channel or groove defined by two deflectable walls is enhanced by squeezing a liquid-repellant type of cement or adhesive into the groove, this helps to seal the periphery of the device to the person wearing it.

3. A device according to claim 1 in which the said deflectable walls define a saddle configuration designed to contact the wearer between the base of the vagina and the anus and located at the rear zone of the device in order to minimise the possibility of leakage at this area.

4. A device according to claim 1 or 2 including an undercut region located beneath the deflectable walls intended to limit splash back, and having an overall "waisted" or "8-shaped" configuration as seen in plan to improve comfort in wear.

5. A device according to claim 4 which includes a basin or chamber shaped to conduct all urine directly to an outlet pipe.

6. A device according to claim 2 in which the non-irritant cement or adhesive material is a material which can be squeezed from a tube or moulded by hand from a block and which when applied to moist body skin surfaces, is capable of adhesively adhering thereto for a prolonged period of time, for example, well over 12 hours, and which, when so used, does not generate any allergic reaction or irritation in the majority of human beings when so adhered.

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